

REMARKS

Applicants request a five-month extension of time for filing this submission and enclose a check in payment of the fee under 37 CFR § 1.17(a)(5).

Claims 23 and 24 have been added. These claims find support in the specification, for example, at Column 4, lines 9-38.

Claims 1-3 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter not enabled by the specification. The Examiner has alleged that support and examples for the phrase “cyclic aliphatic aromatic” groups is not provided, and that the skilled artisan could not ascertain physiological activity of these compounds without undue experimentation.

Applicants respectfully submit that the claimed methods of using compounds in which “substituent Z is a hydrocarbon group selected from the group of cyclic aliphatic, aromatic, or a combination of aliphatic and aromatic hydrocarbon” are supported by an enabling disclosure in the specification, and that the skilled artisan can make and use such compounds in the absence of undue experimentation.

The Examiner has alleged that “the specification only mentions that Z is a “cyclic aromatic aliphatic group.” Office Action mailed June 24, 2004 at p. 2. Applicants respectfully disagree. The specification discloses, for example, at Column 2, lines 31-49, compounds of Formula I in which the Z substituent at carbon 16 may be a cyclic aliphatic hydrocarbon, an aromatic hydrocarbon, or a combination thereof. The terms “cyclic aliphatic” and “aromatic” are well-known to and understood by those of ordinary skill in the art, and thus the present disclosure is sufficient to satisfy the requirements of 35 U.S.C. § 112, first paragraph. It is well-established that a patent need not teach, and preferably omits, that which is well-known in the art. In re Wands, 858 F.2d 731, 735, 8 U.S.P.Q.2d 1400, 1402 (Fed. Cir. 1988); , 858 F.2d 731, 735, 8 U.S.P.Q.2d 1400, 1402 (Fed. Cir. 1988); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384, 231 U.S.P.Q. 81, 95 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987).

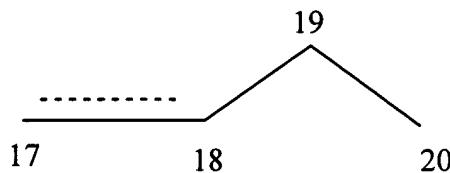
The specification further sets forth, at Col. 3, lines 57-60, an example of a Z substituent that is a combination of an aliphatic and aromatic hydrocarbon, i.e., a methyl phenyl group. Claim 22 is directed to a method utilizing a compound of the invention in which Z is a methyl phenyl group, has been added. In addition, the specification teaches one of skill in the art to

identify compounds having the ability to decrease intraocular pressure, for example at Col. 4, line 52 – Col. 5, line 12. As disclosed therein, a single dose of the compound of the invention is applied to glaucomatous monkey eyes. Intraocular pressure is measured before and after application in order to identify compounds that decrease intraocular pressure. The specification thus provides considerable guidance, and the assay is routine and uncomplicated. A considerable amount of Experimentation is permissible where, as herein, it is merely routine or the specification provides a reasonable amount of guidance. In re Wands, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988). Thus the claims meet the enablement requirements of 35 U.S.C. § 112, first paragraph. Accordingly, withdrawal of the rejection of Claims 1-3 under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Claims 1-3 and 22 stand rejected under 35 U.S.C. § 103(a) as allegedly rendered obvious by U.S. Patent No. 6,124,353 to Woodward. The Examiner has alleged that Woodward teaches the use of prostaglandins for the treatment of ocular hypertension, and that it would have been obvious to substitute a cyclic aliphatic group, an aromatic group, or a combination of an aliphatic and aromatic hydrocarbon of the compounds of the present invention for the aliphatic group of the compounds of Woodward at the Z position.

Applicants respectfully submit that the subject matter of the claims is not obvious in view of Woodward, because one of ordinary skill in the art would not have been motivated to substitute the Z substituent of the present invention for the aliphatic hydrocarbon substituent of the compounds of Woodward.

In each of the prostaglandin compounds disclosed by Woodward, the group that corresponds to the Z substituent of the compounds of the present invention is an aliphatic hydrocarbon having four carbons. This straight chain hydrocarbon is represented by Woodward as follows, wherein the dotted line between C-17 and C-18 indicates a single or double bond:



This substituent in the prostaglandin compounds of Woodward is the same as the C-17 to C-20 chain in the naturally occurring prostaglandins.

In contrast, in the compounds of the present invention, the straight-chain C-17 to C-20 group is replaced by a hydrocarbon group selected from the group of cyclic aliphatic, aromatic, or a combination of aliphatic and aromatic hydrocarbon, i.e., the Z substituent. The Z substituent in the compounds of the present invention is not contained in naturally occurring prostaglandins.

There is neither implicit nor explicit suggestion in Woodward to substitute the present Z substituent for the naturally occurring prostaglandin component present in Woodward's compounds. Further, the present rejection under 35 U.S.C. § 103(a) is silent as to the source of the motivation for one of ordinary skill in the art to make such a substitution. The Examiner has merely alleged that “[t]he substitution of an aliphatic group for a cyclic aliphatic group would have been obvious to a person skilled in the art in the absence of evidence to the contrary.” Office Action mailed April 4, 2003 at p. 4.

To establish obviousness, there must be some motivation, suggestion or teaching of the desirability of making the specific combination. In re Kotzab, 208 F.3d 1365, 1370, 54 U.S.P.Q.2d 1308, 1316 (Fed. Cir. 2000). The mere fact that references can be modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. In re Mills, 916 F.2d 680, 682, 16 U.S.P.Q.2d 1430, 1432 (Fed. Cir. 1990). See also M.P.E.P. § 2143.01. In making the assessment of differences between the prior art and the claimed subject matter, 35 U.S.C. § 103 specifically requires consideration of the claimed invention “as a whole.” This “as a whole” instruction prevents evaluation of the invention part by part. Ruiz v. A.B. Chance Co., 357 F.3d 1270, 1275, 69 U.S.P.Q.2d 1686, 1690 (Fed. Cir. 2004). Without this requirement, an obviousness assessment might break the invention into its component parts, then find a prior art reference corresponding to each component. This improper method would import hindsight into the obviousness determination by using the invention as a roadmap to find its prior art components. Princeton Biochemicals, Inc. v.

Beckman Coulter, Inc., No. 04-1493, slip op. at 8 (Fed. Cir. June 9, 2005). Simply identifying all of the elements in a claim in the prior art does not render a claim obvious. 35 U.S.C. § 103 requires some suggestion or motivation in the prior art to make the new combination. Id. at 10. Because there is no suggestion or motivation in the prior art to modify the teaching of Woodward, a prima facie case of obviousness has not been established. Accordingly, a prima facie case of obviousness has not been established. Withdrawal of the rejection of Claims 1-3 and 22 under 35 U.S.C. § 103(a) is respectfully requested.

In view of the foregoing remarks and amendments, it is respectfully submitted that the present application is in condition for allowance. Favorable consideration of all pending claims is earnestly solicited.

Respectfully submitted,

DORSEY & WHITNEY LLP

By: 

Gary Abelev (Reg. No. 40,479)
250 Park Avenue
New York, NY 10177
(212) 415-9200

Date: July 27, 2005

4836-2734-8224\1